DEPARTMENT OF HEALTH AND HUMAN SERVICES

Using and Maintaining Documents and Records

Finding the information when you need it

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Problem Scenario

- You are the laboratory supervisor in a moderate-sized hospital. A physician calls you and says that he has a patient who had a potassium of 5.5 mmol/L yesterday and 3.5 today. The patient had not received any change of medication or diet.
- What documents or records would you review to find the source of the problem?

Outline

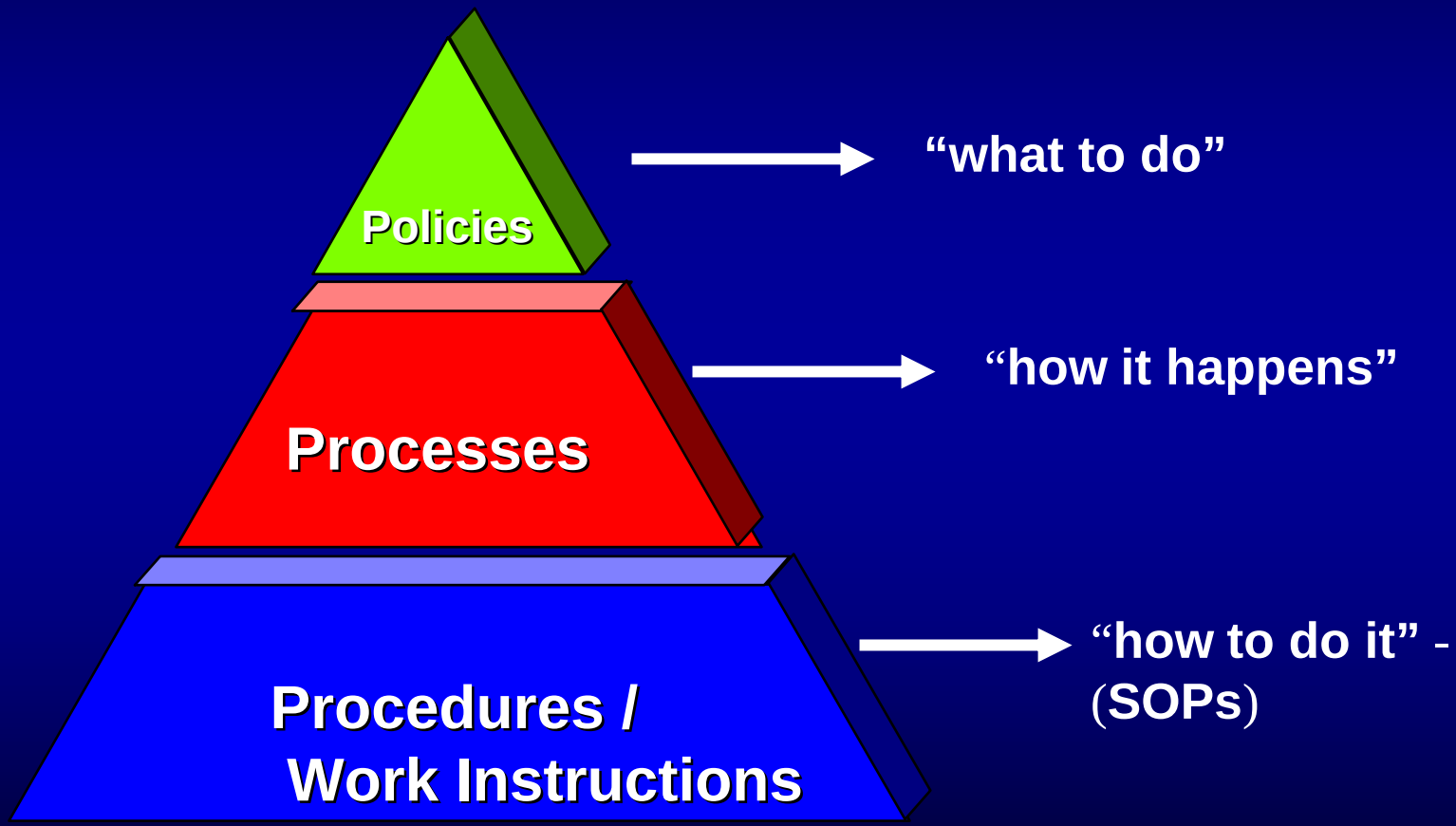
- Definitions
- Importance of documents
- Document types
- Document preparation
- Control of Document and records

Definitions

- Documents: written policies, process descriptions, procedures, and blank forms
  - Used to communicate information
- Records: worksheets, forms, charts, labels,
  - Used to capture information, activities, or results when performing a procedure
- May be paper or electronic

Documents

Hierarchy of Documents



Policies

- The “WHAT TO DO”
  - Statements of the organization's intent
  - Framework for the organization’s Quality Manual

Processes

- The “HOW IT HAPPENS”
  - Describes the steps involved to carry out quality policies
  - Easily represented in flow charts
  - Involves a series of steps, usually occurring over a period of time

Procedures / Work Instructions

- The “HOW TO DO IT”
  - The step-by-step instructions for performing a single activity

Why Do Labs Need Documents?

- Policies - communicate to customers
- Quality Manual for monitoring the total testing process
- Procedure manuals – consistent methods
- References - available to share or access
- Required to meet formal laboratory standards

Why do labs need documents?

- Verbal instructions often are:
  - Not heard
  - Misunderstood
  - Quickly forgotten
  - Ignored

Standard Operating Procedures Common Elements:

- Title
- Purpose
- Procedure instructions
  - Pre-analytic
  - Analytic
  - Post-analytic
- References
- Author
- Approval signature (s)

Good Documents Are:

- Clear
- Concise
- User friendly

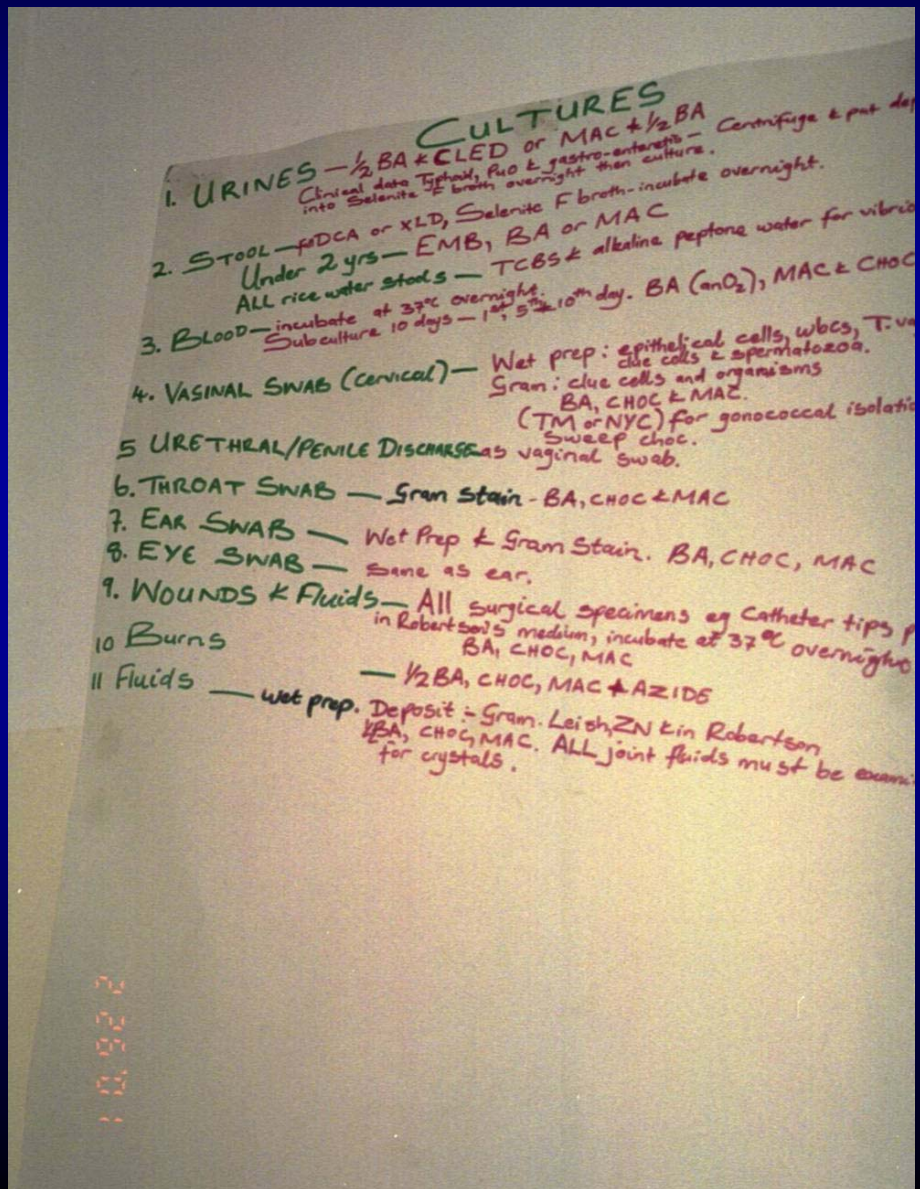
Avoid Drowning in Detail…..

- BAD EXAMPLE: “The purpose of this procedure is to document the aforementioned activities, herin after referred to as the prescribed tasks in terms that preclude their execution in an inconsistent manner, wherin such inconsistency may potentially result in the prescribed tasks delivering a result that is not repeatable or reproducible”

And Poorly Written Procedures

- Why use ten words when one will do?
  - “The items hereinunder referenced in some cases fell excessively outside normal parameters.”
  - “The procedures contained herin are applicable to all operations in the following departments within their functional ambit”

Job Aid



CULTURES

1. URINES — ½ BA & CLED or MAC & ½ BA
   Clinical data Typhoid, Pus & gastro-enteritis — Centrifuge & put dep
   into Selenite F broth overnight then culture.
2. STOOL — MDCA or XLD, Selenite F broth - incubate overnight.
   Under 2 yrs — EMB, BA or MAC
   ALL rice water stools — TCBS & alkaline peptone water for vibrio
3. BLOOD — incubate at 37°c overnight.
   Subculture 10 days — 1st, 5th & 10th day. BA (anO_2), MAC & CHOC
4. VAGINAL SWAB (cervical) — Wet prep: epithelial cells, wbcs, T. va
   clue cells & spermatozoa.
   Gram: clue cells and organisms
   BA, CHOC & MAC.
   (TM or NYC) for gonococcal isolatio
5. URETHRAL/PENILE DISCHARGE as vaginal swab.
   Sweep choc.
6. THROAT SWAB — Gram Stain - BA, CHOC & MAC
7. EAR SWAB — Wet Prep & Gram Stain. BA, CHOC, MAC
8. EYE SWAB — Same as ear.
9. WOUNDS & Fluids — All surgical specimens eg Catheter tips p
   in Robertson's medium, incubate at 37°c overnight
   BA, CHOC, MAC
10. Burns — ½ BA, CHOC, MAC & AZIDE
11. Fluids — wet prep. Deposit - Gram. Leish, ZN & in Robertson
    ½BA, CHOC, MAC. ALL joint fluids must be exam
    for crystals.

AFB Smear Staining

1

Always use new, grease free, and clean slides
Correctly label slides with stylus or lead pencil.

2

Fish out yellowish portion from sputum container and place on slide with the rough end of the stick.

3

Spread material evenly in an approximate area of 2cm X 1cm so that news print is readable on drying.

4

Air dry smear completely and then heat fix smear in a flame.

5

Place slides on the staining rack without touching each other. Always add Positive and Negative control slides.

6

Cover slides with freshly filtered carbol fuchsin.

7

Heat gently with a torch until steam rises from the slides. Stain for five minutes.

8

Wash gently with water.

9

Drain the water.

10

Cover slides with decolorizing solution for three minutes.

11

Wash throughly with water. If slide is not decolorized properly repeat step 10 for additional 1-3 minutes. Rinse throughly with water.

12

Drain the water.

13

Cover with counter stain Methylene blue for one minute.

14

Drain the counter stain.

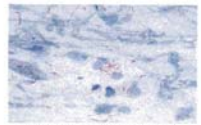
15

Wash with water. Wipe the back side of slides with tissue paper.

16

Air dry the slides in a rack.

17



View the smear under oil immersion.
AFB: Fine, red rods against blue background.

18

AFB Counts	Recording/Reporting
No AFB in at least 100 fields	0/negative
1 to 9 AFB in 100 fields	Actual AFB count
10 to 99 AFB in 100 fields	+
1 to 10 AFB per field in at least 50 fields	++
>10 AFB per field in at least 20 fields	+++

Report the findings as per WHO and IUATLD recommendations.

A joint effort of:

RIT The Research Institute of Tuberculosis Japan

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Records

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Why are Records Essential?

- For continuous monitoring of quality system
- For specimen tracking throughout process
- To identify failures in equipment
- To revisit information; reference
- For use as a management tool

Examples:
Quality Assurance Records

- Specimen log book, registers
- Laboratory workbooks/sheets
- Instrument printouts –maintenance records
- QC
- EQA / PT records
- Patient test reports

Other Examples: Quality Assurance Records

- Personnel
- Results of internal audits
- Results of external audits
- Continuous improvement projects
- User surveys and customer feedback

Things You Might Forget to Record!

- Disposition of rejected specimens
- Referral of specimens to another laboratory
- Records of adverse occurrences or problems
- Inventory and storage records
- Instrument purchase data, preventive maintenance, troubleshooting

Test Report Contents

- Date and time
- Any patient identifiers
- Date and time of sample collection
- Date and time sample received in the lab
- Person performing test
- Biological reference intervals
- Interpretative comments
- Laboratory name
- Name of person authorizing the report
- Name and lot number of kit or reagent
- QC for the test run

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Document / Record Control

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Document Control

- Advantages:
  - Assures that the most current version is used
  - Ensures availability when needed
  - Organizational tool

Document Control Elements

- A system for formatting and maintaining documents
  - Uniform format
    - Legible and identifiable
  - Approval, distribution, and revision process
    - Reviewed and updated
  - Master log
  - Availability
    - Relevant versions at point of use
  - Archive

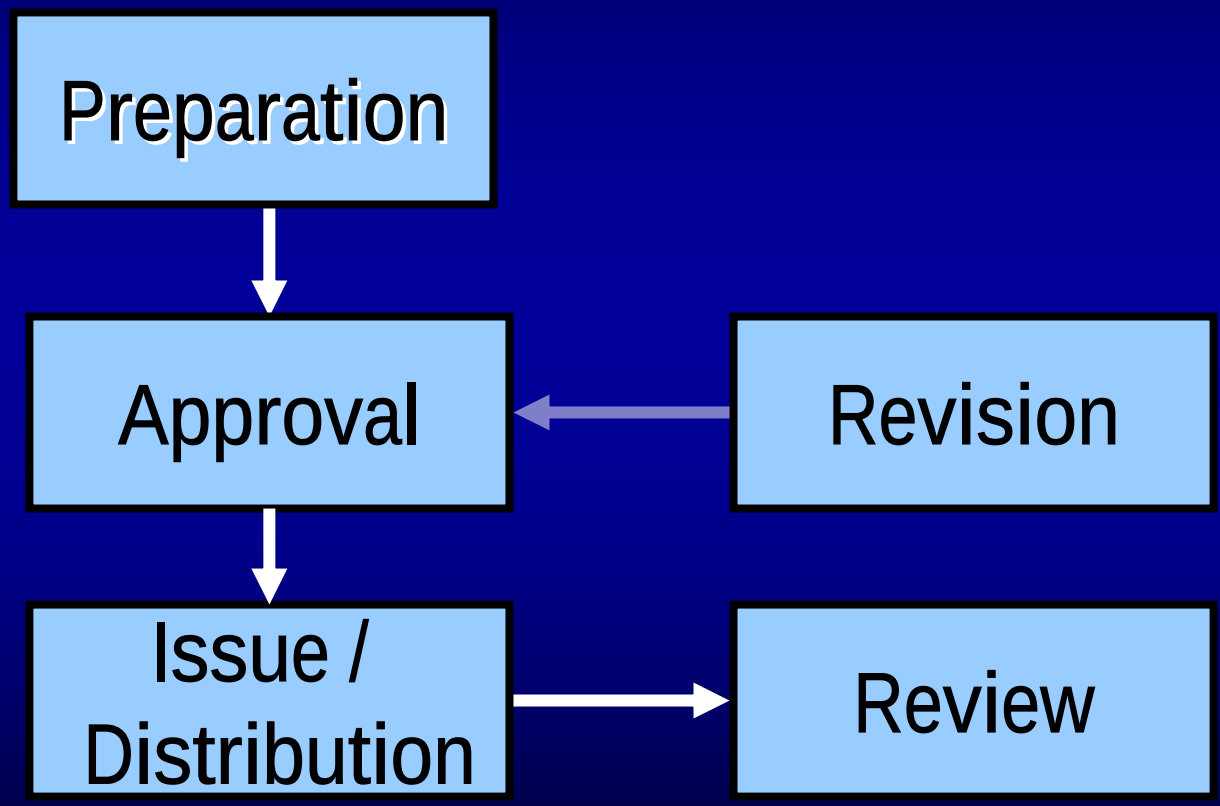
Documents of External Origin

- Include in your document control system:
  - Instrument service manuals
  - Industry regulations
  - ISO standards
  - References used for your documentation

Implementation Steps

- Collect existing documents and records
- Review and update
- Determine additional needs
- Develop or obtain
  - Documents, forms, worksheets, logbooks, reports
  - Involve stakeholders

Summary: Document Preparation and Control Process



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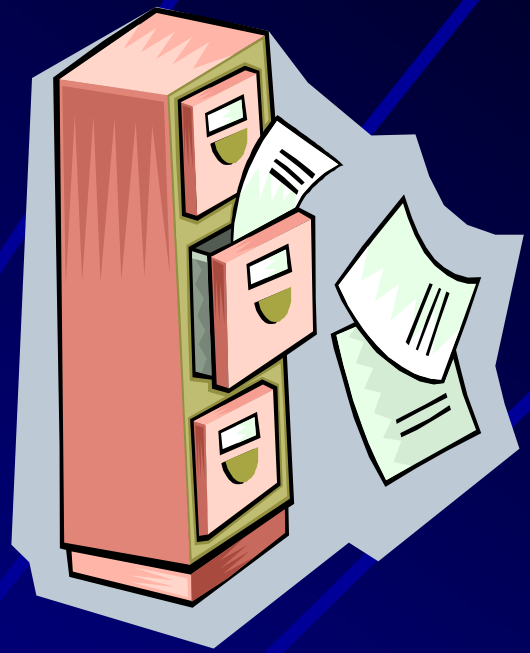
Where will you keep your documents and records?



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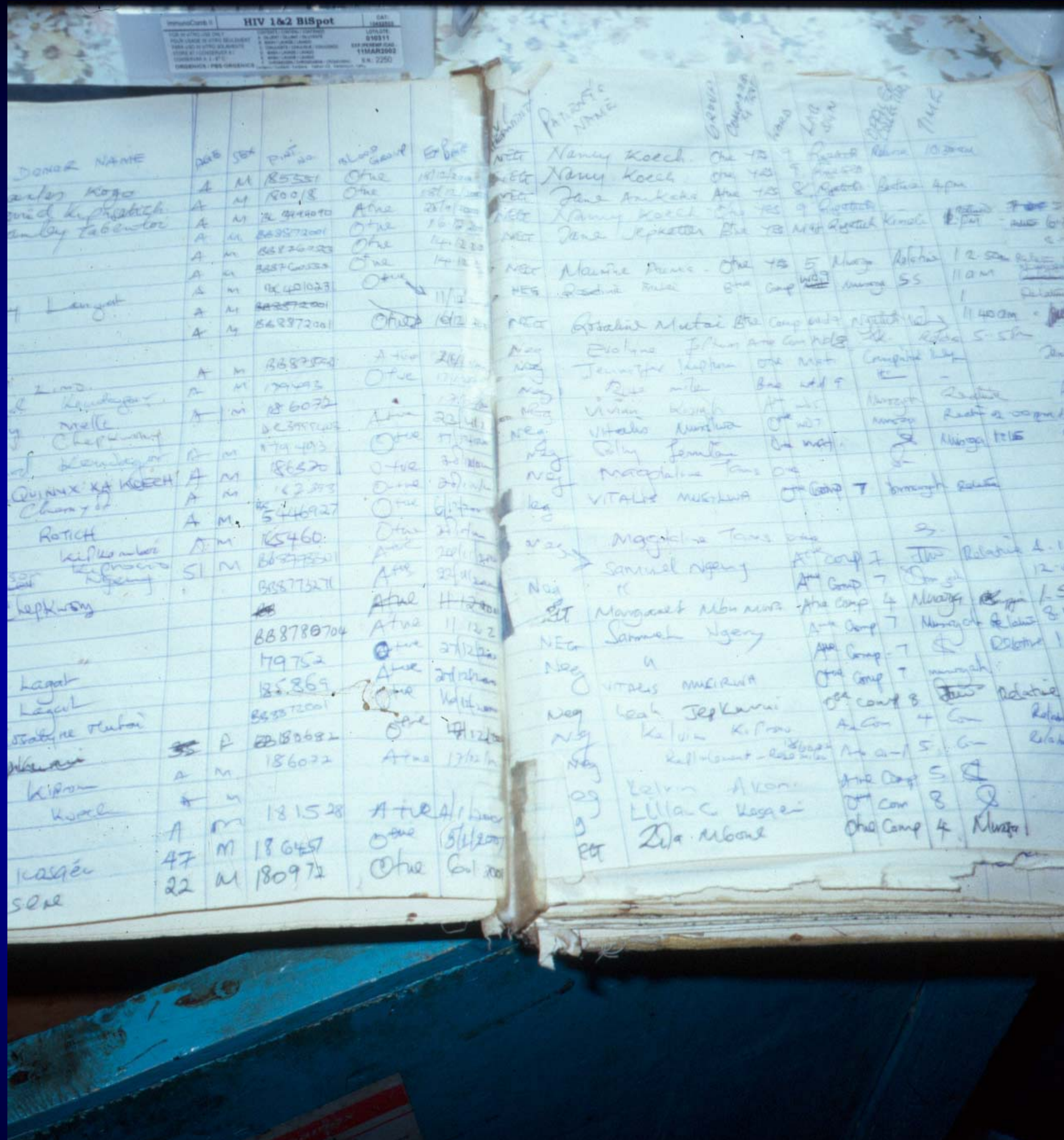
Paper Systems

- Permanence
  - books bound
  - pages numbered
  - permanent ink
  - controlled storage
- Security
  - controlled distribution confidentiality
  - safe from environmental hazards
- Ability to attribute
  - all retained records should be signed and dated, periodically signed by supervisor



HIV 1&2 BiSpot
DONOR NAME

Electronic Systems

- Permanence
  - system maintenance, e.g., backups
- Security
  - Access
  - Confidentiality
- Ability to attribute

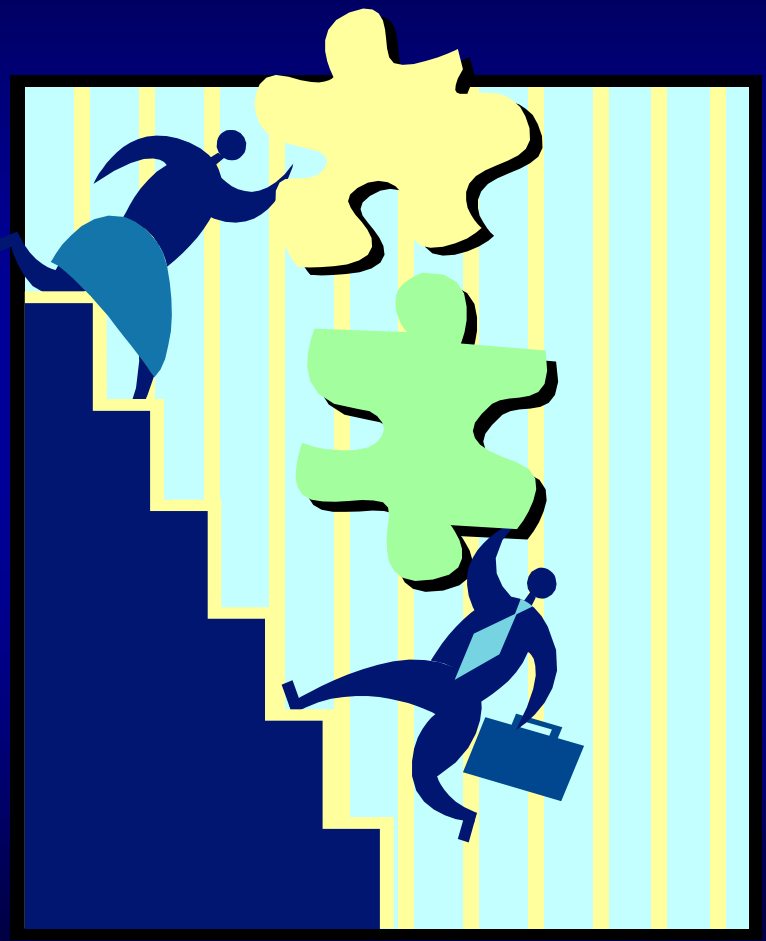
Factors Affecting Retention Times

- Review of the testing process
- National legislation and regulation
- Research purposes
- Time intervals between assessments or audits

Common Problems

- Approval
- Distribution
  - Too many documents are distributed. The system cannot be maintained.
- Lack of control of documents of external origin
- Avoid these problems by planning ahead……..

And all the pieces will fall in place.



“Take home” Messages

- Written policies and procedures are the backbone of the quality system
- Reliable and timely reports of results can save lives
- Complete quality assurance records make quality management possible

Back to Problem Scenario

- Were all of the steps you needed to review part of your current documentation system?
- Do you see how some of the records suggested here could help you find the source of the problem?
- Would you start keeping more records than you did before?